

117TH CONGRESS
2D SESSION

H. R. 7473

To prohibit pharmaceutical manufacturers from interfering with therapeutically equivalent or interchangeable substitution decisions by health care providers to limit competition from a generic drug or biosimilar biological product, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 7, 2022

Mrs. CAROLYN B. MALONEY of New York (for herself, Mr. CICILLINE, Mr. NADLER, Mr. WELCH, Ms. SCHAKOWSKY, Ms. PORTER, Mr. DESAULNIER, and Mr. RASKIN) introduced the following bill; which was referred to the Committee on the Judiciary

A BILL

To prohibit pharmaceutical manufacturers from interfering with therapeutically equivalent or interchangeable substitution decisions by health care providers to limit competition from a generic drug or biosimilar biological product, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Generic Substitution
5 Noninterference Act”.

1 **SEC. 2. DECLARATION OF PURPOSES.**

2 The purposes of this Act are—

3 (1) to enhance competition in the pharmaceutical market by stopping anticompetitive practices
4 that limit or prevent competition from generic drugs
5 and biosimilar biological products,

6
7 (2) to support the purposes and intent of antitrust law by prohibiting anticompetitive practices in
8 the pharmaceutical industry that harm consumers,
9 and

10
11 (3) to preserve physician autonomy.

12 **SEC. 3. INTERFERENCE WITH PROVIDER SUBSTITUTION**

13 **DECISIONS.**

14 (a) PROHIBITION.—It shall be unlawful for a pharmaceutical manufacturer—

15
16 (1) to provide any item or service, or anything
17 of value, for the purpose of aiding or assisting a
18 health care provider to request or direct that a drug
19 be dispensed “as written” or “brand name only”
20 when a generic drug or biosimilar biological product
21 is available, including any prescription notepad or
22 prescription stamp, but not including any product
23 sample, or

24
25 (2) to direct a health care provider to write
26 “dispense as written”, “brand name only”, or another similar notation or direction on a prescription

1 when a generic drug or biosimilar biological product
2 is available.

3 (b) LIMITATION.—Nothing in this section prevents a
4 health care provider from exercising the provider's own
5 medical judgment to prescribe any drug or biologic prod-
6 uct.

7 (c) CIVIL PENALTY ACTIONS.—If the Commission
8 has reason to believe that a pharmaceutical manufacturer
9 has violated or is violating this Act, the Federal Trade
10 Commission may commence a civil action to recover a civil
11 penalty and seek other appropriate relief in a district court
12 of the United States against the pharmaceutical manufac-
13 turer. Except as otherwise provided in section 16(a)(2) of
14 the Federal Trade Commission Act (15 U.S.C. 56(a)(3)),
15 the Commission shall have exclusive authority to com-
16 mence or defend, and supervise the litigation of, any civil
17 action under paragraph (1) and any appeal of such action
18 in its own name by any of its attorneys designated by it
19 for such purpose, unless the Commission authorizes the
20 Attorney General to do so. The Commission shall inform
21 the Attorney General of the exercise of such authority and
22 such exercise shall not preclude the Attorney General from
23 intervening on behalf of the United States in such action
24 and any appeal of such action as may be otherwise pro-
25 vided by law. The civil penalty shall be sufficient to deter

1 violations of this section, but in no event shall be greater
2 than three times the gross revenues received for sales of
3 the brand-name drug during the period in which the pro-
4 hibited conduct occurred. In determining the amount of
5 the civil penalty, the court shall take into account—

- 6 (1) the nature, circumstances, extent, and grav-
7 ity of the violation with respect to the pharma-
8 ceutical manufacturer,
9 (2) the degree of culpability,
10 (3) the history of violations,
11 (4) the ability to pay, and any effect on the
12 ability to continue doing business, and
13 (5) other matters that justice requires.

14 (d) UNFAIR METHOD OF COMPETITION.—A violation
15 of this Act shall also constitute an unfair method of com-
16 petition under section 5(a)(1) of the Federal Trade Com-
17 mission Act (15 U.S.C. 45(a)(1)).

18 (e) ENFORCEMENT AUTHORITY.—Except as other-
19 wise provided in subsection (c), the Commission shall en-
20 force this Act in the same manner, by the same means,
21 and with the same jurisdiction, powers, and duties as
22 though all applicable terms and provisions of the Federal
23 Trade Commission Act (15 U.S.C. 41 et seq.) were incor-
24 porated into and made a part of this Act.

25 (f) ACTIONS BY STATES.—

1 (1) IN GENERAL.—In any case in which the at-
2 torney general of a State has reason to believe that
3 an interest of the residents of that State has been
4 or is threatened or adversely affected by the engage-
5 ment of a pharmaceutical manufacturer in any con-
6 duct described in subsection (a), the State, as
7 parens patriae, may bring a civil action on behalf of
8 the residents of the State in a district court of the
9 United States of appropriate jurisdiction to enjoin
10 that practice, to obtain damages, restitution, or
11 other compensation on behalf of residents of such
12 State, or to obtain such further and other relief as
13 the court may deem appropriate.

14 (2) NOTICE.—The State shall serve prior writ-
15 ten notice of any civil action under this subsection
16 upon the Commission and provide the Commission
17 with a copy of its complaint, except that if it is not
18 feasible for the State to provide such prior notice,
19 the State shall serve such notice immediately upon
20 instituting such action. Upon receiving a notice re-
21 specting a civil action, the Commission shall have
22 the right to—

23 (A) intervene in such action,
24 (B) upon so intervening, to be heard on all
25 matters arising therein, and

1 (C) to file petitions for appeal.

18 (5) VENUE; SERVICE OF PROCESS.—Any civil
19 action brought under this subsection in a district
20 court of the United States may be brought in the
21 district in which the defendant is found, is an inhab-
22 itant, or transacts business or wherever venue is
23 proper under section 1391 of title 28. Process in
24 such an action may be served in any district in

1 which the defendant is an inhabitant or in which the
2 defendant may be found.

3 (g) DEFINITIONS.—In this section:

4 (1) ANTITRUST LAWS.—The term “antitrust
5 laws” has the meaning given the term in subsection
6 (a) of the 1st section of the Clayton Act (15 U.S.C.
7 12(a)).

8 (2) BIOSIMILAR BIOLOGICAL PRODUCT.—The
9 term “biosimilar biological product” means a biologi-
10 cal product licensed under section 351(k) of the
11 Public Health Service Act.

12 (3) BRAND NAME DRUG.—The term “brand
13 name drug” means a drug approved or licensed
14 under section 505(c) of the Federal Food, Drug, and
15 Cosmetic Act or section 351(a) of the Public Health
16 Service Act.

17 (4) GENERIC DRUG.—The term “generic drug”
18 means a drug approved under section 505(j) of the
19 Federal Food, Drug, and Cosmetic Act.

20 (5) HEALTH CARE PROVIDER.—The term
21 “health care provider” means any individual or enti-
22 ty, including any pharmacy, that participates in any
23 Federal health care program (as defined in section
24 1128B(f)) of the Social Security Act.

1 (6) PHARMACEUTICAL MANUFACTURER.—The
2 term “pharmaceutical manufacturer” means the
3 holder of—

4 (A) an application approved under section
5 505(c) or 505(j) of the Federal Food, Drug,
6 and Cosmetic Act, or

7 (B) a license under section 351(a) or
8 351(k) of the Public Health Service Act.

9 (h) RULE OF CONSTRUCTION.—Except to the extent
10 this Act establishes an additional basis for liability en-
11 forced as provided herein, nothing in this Act shall modify,
12 impair, limit, or supersede the applicability of the anti-
13 trust laws, as defined in subsection (a) of the 1st section
14 of the Clayton Act (15 U.S.C. 12(a)), and of section 5(a)
15 of the Federal Trade Commission Act (15 U.S.C. 45(a)).
16 Nothing in this Act shall be construed to limit the author-
17 ity of the Federal Trade Commission under any other pro-
18 vision of law.

19 (i) SEVERABILITY.—If any provision of this Act, or
20 the application of such provision, to any person or cir-
21 cumstance is held to be unconstitutional, the remainder
22 of this Act, and the application of the remaining provisions
23 of this Act, to any person or circumstance shall not be
24 affected.

